



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Linda DeLuise

From: Dee Colby, Ph.D., Entomologist

A handwritten signature in blue ink, appearing to read "D. Colby", is placed next to the "From:" line.

Secondary Review: Jennifer Saunders, Ph.D, Senior Entomologist

A handwritten signature in blue ink, appearing to read "J. Saunders", is placed next to the "Secondary Review:" line.

Date: 2016-June-27

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 433867

Decision no.: 513149

Submission no: 984818

Action code: R310

Product Name: Multifly Feed-Thru Control For Horses

EPA Reg. No or File Symbol: 91368-R

Formulation Type: RTU pellets

Ingredients statement from the label with PC codes included:

Novaluron (0.5%) PC: 124002

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m² or mg/cm² or mg/kg body weight as appropriate):

Use Patterns: Daily doses of 25 mg novaluron/100 lbs body weight or 1.8 mg novaluron/kg body weight/day

I. Action Requested: Registrant requested an efficacy review of the submitted MRID to determine if data support product efficacy for claims to prevent development of stable flies and house flies in horse manure.

II. Background: Registrant is proposing an R310 for registration of a new end use product requiring data review to support IGR claims for stable flies and house flies. A single MRID specific to novaluron 0.25% was submitted to bridge support of product efficacy claims for the above mentioned public health pests for novaluron (0.5%).

III. MRID Summary:

MRID 49892701. Sharp, M. (2007) The ability of a pelleted ready-to-use supplement comprised of 0.25% w/w Novaluron in an alfalfa base to prevent hatching of biting and nuisance fly eggs.

(1) GLP

(2) **Methods:** This is a live animal/lab study conducted in Vernon, TX. The study was conducted using 12 horses, 6 treated and 6 control, with relatively equal body weight between the two groups. Treated horses were fed 33 g of 0.2185% novaluron, for a rate equivalent to 0.25% novaluron, impregnated alfalfa pellets mixed with 5 lbs of grain daily for 7 d; controls were fed in the same manner minus the active ingredient. Daily dose rates were 0.13-0.16 mg novaluron/kg body weight. Following the 7 d feeding, 260 g of manure from each horse were placed into open containers in areas easily accessible to natural infestations of stable and house flies for oviposition. After 4 d, containers were then covered with screen and incubated for 20 d in the lab. Hatched flies, were identified and counted along with a record of any sub-adult life stages present at 7 and 20 d post exposure to adult flies.

(3) **Results:** Feces of horses treated with novaluron for 7 d contained 0 adult flies, pupae or larvae. Feces from control horses contained, in total, 52 house flies (*Musca domestica*), 20 stable flies (*Stomoxys calcitrans*), 108 unemerged diptera pupae, one larva, and 11 'other' diptera.

(4) **Conclusion:** This MRID is **acceptable**; daily doses of the tested product containing, 0.25% novaluron, at 0.13-0.16 mg novaluron/kg body weight prevent emergence of adult house flies and stable flies on manure. Persistence of novaluron within the animal and/or within manure to determine residual effects on emergence of listed flies was not tested. Also, this product is not a repellent or adulticide; it does not offer protection from adult house flies and stable flies.

IV. EXECUTIVE DATA SUMMARY:

(A) The submitted data support that daily doses of novaluron (0.25%) at 0.13-0.16 mg novaluron/kg body weight prevent adult stable fly (*Stomoxys calcitrans*) and house fly (*Musca domestica*) emergence. This data may be bridged to support efficacy of daily doses of novaluron (0.5%) at 1.8 mg novaluron/kg body weight on listed fly emergence. Multifly Feed-Thru Control For Horses with novaluron (0.5%) is not a repellent or adulticide; it does not offer protection from adult house flies and stable flies.

Efficacy claims are not supported for gnats.

V. LABEL RECOMMENDATIONS:

(1) Directions for use: see attached label for comments.

(2) The following marketing claims are acceptable: see attached label for comments.

(3) The following marketing claims are unacceptable: see attached label for comments.

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: N/A

MultiFly™ Feed -Thru Fly Control [For Horses]

Fly-Defy™ Feed-Thru Fly Control [For Horses]

Fly-Defy Plus™ Feed-Thru Fly Control [For Horses]

Horse Logic™[(specific combo)]+MultiFly Daily Pack™-

MultiFly + Horse Logic- Seasonal Daily Pack

MultiFly Seasonal Daily Pack

Horse Logic™ Plus Feed-Thru Fly Control [For Horses]

- 0.5 % Novaluron Equine Feed-thru [Listed](#) Fly Control Feed Additive
- ~~Image of Fly Cycle with line through it.~~
- Pre Measured Daily Pack
- Accurate and Easy Dosing
- Feed Thru [Listed](#) Fly Control for Horses
- Pre Measured Pouches
- ~~Seasonal Fly Control Protection~~
- Daily Feed on .88 oz pouch [for horses under 1100 lbs]
- Easy, Accurate Pre-Measured Daily Packs
- ~~One pack a day keeps the flies away~~
- Daily feed-through [listed](#) (fly larvacide)(fly control)(for horses)]
- Prevents the development of stable flies and house flies in the manure of treated horses
- [Highly Palatable Feed Additive] [to Prevent the Development of Stable Flies and House Flies in the Manure of Treated Horses]
- [(Stops)(prevents)(development) of House fly and Stable fly larvae in the manure (of) (from) treated horses]
- [Contains (novaluron)(IGR)(Insect Growth Regulator) (IGR)(Chitin Synthesis Inhibitor)]
- [Breaks the [listed](#) (fly) life cycle]
- [Contains no (organophosphates)]
- [(Can be used as) part of an integrated pest management program]
- Feed Daily in combination with (Formula 707 Supplements)
- Feed Daily in combination with (Horse Logic Daily Packs)
- Prevents the development of house and stable flies in horses environment
- Creates ~~healthier~~ environment for horses as flies are vectors of infectious ~~disease~~
- ~~Reduces Stress on horses caused by fly infestation~~

Commented [CD1]:
delete graphic. This graphic could imply that all life stages are controlled by this product, which they are not.

Commented [CD2]:
implies residual control for a season; the product is provided daily. Also, this product is not a repellent and therefore does not offer protection from listed flies.

Commented [CD3]:
no data were submitted to support this claim; adult flies may still be present in the area.

Commented [CD4]:
registrant would need to reword without using "healthier". Also, "infectious disease" is too broad; registrant would need to list out the diseases that the tested insects vector.

Commented [CD5]:
this product neither repels nor kills adult flies that may be in the area...presumably causing stress on horses. No data were submitted to support this claim.

- For Multiple Listed Fly Species [House and Stable]
- For Multiple Listed Flying insects [flies & gnats]
- Breaks the listed fly life cycle ~~for up to 6 weeks~~
- The logical stable fly and house fly control solution

ACTIVE INGREDIENT (% by weight)
 Novaluron * (CAS#) 0.5%
 OTHER INGREDIENTS [**] 99.5%
 TOTAL 100.00%

Contains 2.27 gms of novaluron per pound

** Refers only to ingredients which are not larvicidal See Feed Ingredients

Feed Ingredients: Wheat Middling Alfalfa Dehydrated Calcium Carbonate Sodium Chloride and Calcium , Propionate (preservative)

EPA Reg No – 91368-xxx
 EPA Est No - Pending

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET WT 0.88 ounces (28.95 grams)

READ ENTIRE LABEL BEFORE EACH USE

[] and () optional language

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

DO NOT USE ON HORSES INTENDED FOR SLAUGHTER

Feed the ~~recommended~~ specified dosage of [novaluron] [brand name][this product] to each horse separately to make certain it receives the full ration. ~~This~~ Feed this product daily ~~should be fed~~ top dressed on grain or mixed with the horses total rations, to provide 25 mg of novaluron per 100 lbs [45.4 kg] body weight. For occasional finicky eaters who do not accept new feeds readily mix (additional brand name)(this product) with sweet feed or grain rations.

Dosage and Administration for Control of Houseflies and Stable Flies

Begin feeding in the spring before flies begin to appear and continue feeding throughout the summer and into the fall until cold weather inhibits fly development.

Mixing [this product] [brand name]:

Daily Dosage:

Commented [CD6]:

o data were submitted to support product efficacy against gnats.

Commented [CD7]:

ovaluron 0.25% was tested as a feed thru for 7 days with a 4 day exposure of post treatment-manure to egg laying flies. Eggs laid during those 4 days were allowed to develop (or not) over a 20 day observation period. Therefore, the residual effect of novaluron in manure to prevent future (i.e., beyond 4 days) egg development was not investigated.

Commented [CD8]:

se of terms like "Should" and "recommended" in terms of the rate, are not acceptable in Directions for Use.

Bulk: Using scoop supplied with the product, mix one (1) scoop of in the horse's ration every day for horses weighing less than 1100 lbs. For horses over 1100 lbs mix (2) scoops of ([brand name]) in the horse's ration every day.

Pre Measured Pouches- Daily feed one .88 oz pouch for horses under 1100lbs. Daily feed two pre-measured.88 oz pouches for horses weighing more than 1100 lbs.

Pre Measured Pouches blended with daily supplement:

Feed one .88 oz daily ration in combination with Horse Logic supplements daily pack. Each daily supplement combination will weigh between 2oz and 10 oz per daily pack depending on the supplement combination. Feed one Horse Logic Daily Pack +(brand name) feed through fly control per day for horses weighing under 1100 lbs.

(brand name)(This product) contains novaluron an (insect growth regulator)(IGR) which prevents the development of houseflies and stable flies in the manure of treated horses but is not effective against existing adult flies (additional brand name)~~(this product remains active against fly larvae in aging manure for up to 6 weeks- (42days)(11/2 months)~~

Significant results may be observed within 2 weeks, ~~but the full benefit should be realized in 4-6 weeks of administration as the adult fly population dies off.~~

In some cases supplemental fly control measures may be needed in and around paddocks and buildings to control adult house and stable flies which can breed in decaying vegetable matter or silage on premises or migrate in from other areas

(brand name)(This product) should be used as part of an (integrated) (pest)(fly)(control)(management) program aimed at reducing fly populations in the horses environment.

- Remove old and or wet manure from in and around your facility so that it cannot become a breeding ground for flies.
- Reduce areas of moisture around your building especially around manure holding areas.
- Clean up hay spills and maintain proper drainage
- Consult your(veterinarian)(or)(retailer) for program recommendations In order to achieve optimum fly control (additional brand name) (this product) should be used in conjunction with on animal products such as (other)(brand name) (MultiFly) Horse Spray).

STORAGE AND DISPOSAL

Commented [CD9]:

his was not within the scope of the submitted MRID. Monitoring of the adult fly population in an area was not conducted. The submitted data do not support this claim.

Do not contaminate water food or feed by storage or disposal

PESTICIDE STORAGE

Store in original container in a cool dry place inaccessible to children and pets

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility

CONTAINER HANDLING

Non refillable container Do not reuse or refill this container

Completely empty plastic bucket by shaking and tapping sides and bottom to loosen clinging particles Then offer for recycling if available or dispose of in a sanitary landfill or by incineration or if allowed by state and local authorities by burning If burned stay out of smoke

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions to the extent consistent with applicable law Seller makes no other express or implied warranty of Fitness or of Merchantability and no agent of Seller is authorized to do so except in writing and with specific reference to this warranty In no event shall Seller s liability for any breach of Warranty exceed the purchase price of the material as to which claim is made

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